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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/057,171 | 01/25/2002 | Thomas A. Vendola | PC11014AGLK | 5278 |

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01/27/2004

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| EXAMINER |
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HUI, SAN MING R

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| ART UNIT | PAPER NUMBER |
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1617

DATE MAILED: 01/27/2004

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/057,171

Applicant(s)

VENDOLA, THOMAS A.

Examiner

San-ming Hui

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendments filed October 29, 2003 have been entered.

Claims 1-38 are pending.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 33-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Hanes et al. (US Patent 5,855,913).

Hanes et al. teaches porous particulate for drug delivery (See claim 1; col. 11, line 55 – col. 15, line 42: Example 2).

Claims 33-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Straub'698 (US Patent 5,853,698).

Straub'698 teaches porous pharmaceutical particles for imaging (col. 7, line 9 – col. 9, line 34).

Claims 33-37 are rejected under 35 U.S.C. 102(e) as being anticipated by Straub'300 (US Patent 6,395,300).

Straub'300 teaches porous pharmaceutical particles for drug delivery (See the abstract). Straub'300 also teaches that such particles be made to become tablet (See particularly the abstract).

Response to arguments

Applicant's arguments filed October 29, 2003 averring the herein claimed composition is prepared from a different method have been considered, but are not found persuasive. Please note that the instant claims 33-37 are drawn to a composition claims. The different methods of preparing the same do not distinguish the final compositions from one to the other. In other words, the method of preparation in claims that drawn to composition does not lend patentable weight unless the applicant can demonstrate the composition prepared by the instant method is structurally different than that prepared by the methods taught in the cited prior art.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-32 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Straub'300 in view of Remington (Remington's Pharmaceutical Sciences, 18th ed., 1990, pages 1633-1647), Remington is of record.

Straub'300 teaches a method of preparing porous pharmaceutical microparticles by mixing the drug with solvents and a pore forming agent to form emulsion, and then evaporate the solvent and the pore forming agent to form the microparticles (See the abstract; also col. col. 11, line 47 – col. 13, 46; claim 1). Straub'300 also teaches the particles of porous matrix can be formulated further into a tablet (See particularly col. 13, line 39). Straub'300 teaches that the pore forming agent as ammonium bicarbonate (See claim 7). Straub'300 also teaches the amount of the solid pore forming agent as 10 to 100% of that of the active drug (See col. 11, line 45).

Straub'300 does not teach the wet or dry granulation method being employed. Straub'300 does not expressly teach the compression of the tablet being employed. Straub'300 does not teach the employment of a compressive agent into the composition. Straub'300 does not teach the herein claimed amount for the solid volatilizable agent.

Remington teaches that wet and dry granulation method is a well-known, commonly used methods of preparation for tablets (See page 1641, col. 2 – page 1644,

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col. 2, last paragraph). Remington also teaches compressible sugars such as lactose, sucrose, and starch can be used for direct compression (See page 1645, col. 2, last paragraph).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ wet and dry granulation method and incorporate a compressive agent into the method of Straub'300. It would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare a tablet by further compressing the porous particles of Straub'300.

One of ordinary skill in the art would have been motivated to employ wet and dry granulation method and incorporate a compressive agent into the method of Straub'300 because the wet and dry granulation and incorporating compressive agents are well-known in the art to be useful for formulating a tablet. Employing well-known method and excipients in formulating pharmaceutical composition would be obvious as being within the purview of skilled artisan.

One of ordinary skill in the art would have been motivated to prepare a tablet by further compressing porous particles of Straub'300. Compression of particles into a tablet is a well-known method for tablet preparation. Straub'300 teaches that the porous particles therein are useful in further processing into tablets. Therefore, employing any well-known method and excipients in formulating pharmaceutical tablet such as compression and the compression aids would be obvious as being within the purview of skilled artisan. Furthermore, the optimization of result effect parameters (amount of excipients employed) is obvious as being within the skill of the artisan.

Response to arguments

Applicant's arguments filed October 29, 2003 averring the instant method not requiring the steps taught in Straub have been considered but are not found persuasive. Although the instant invention does not require the steps taught in Straub, it does not expressly exclude such steps.

Applicant's arguments filed October 29, 2003 averring the failure of Straub to teach the compression steps have been considered, but are not found persuasive. The rejection under 35 USC 103 set forth in the previous office action clearly states that Straub not teaching the employment of compression of the tablet. However, taken the teachings of Remington with Straub, one of ordinary skill in the art would have applied compression to form a tablet since it is well-known to be within the purview of skilled artisan.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (703) 305-1002. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

San-ming Hui
Patent Examiner
Art Unit 1617



SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER

1/23/04